the market formulated out of approximate 600 basie drugs.

(b) WHO's essential drug list of 1985 gives about 350 drugs in different therapeutic heals and when these drug? would be formulated by large number of manufacturers in the country under different dosage forms Mich as tablets, capsules, injections, ointments, oral liquids, the number of formulations moving in the market would appear many. However, the fist of drugs used for Primary Health Centre and sub-centres together is every restrictive and the number does not exceed 58 drugs.

*(c)* Drugs reported to be withdrawn in some countries and continue to be marke ted in other countries do not figure in the WHO list.

(d) and (e) Out of 37 drugs, report ed to be withdrawn in some countries, 19 drugs were never approved to be raarket-ed in I dia, 11 drugs have been withdrawn from the market and remaining 7 Irugs namely, (1) Enteroquinol, (ii) Phenfor-min. (iii) Hydroxyquino!ine derivatives, (iv) Phenylbutazone / Oxyphenbu'azone (v) High dose Lynestrenol products, (vi) Piieraz'ne and (vii) Analgin have been allowed for continued marketing in con-su'ta'ion with experts as the experts felt that there were no adequate rea oning for withdrawal of these drugs and these drugs We cons'deved useful by medical prac titioners.

**Dnugs technical advisory board on the Analgia and its combination**

487. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased *to* refer to Unstar-red Question 2961 given in the Rajya Sabha on the 3rd December, 1986 and state:

(a) whether ban of marketing of Anal-gin has been considered by Drugs Tech nical Advisory Board;

(b) if so, what is the decision arrived at by the Committee;

(c) whether Analgin alone and in com bination with other drugs have been found dangerous and fatal in number of count-ries in different regions, what are the reasons for considering it to be safe in India;

(d) what arc the specific areas where the Sitatio :of India from o countris, where this drag has been ban ned;

(e) whether adverse reports have been published throughout the world; what are the reason, to alow this dangerous drug for human consumption in India;

(f) Whether it ,s a fact that number of subs itute drugs are available in the country without any adver e report; and

(g) if so, what are the names of those drugs?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMI-LY WELFARE (KUMARI SAROJ KHA-PARDH): (a) and (b) The Drugs Technical Advisory Board White examining the justification for continued marketing of Analgin had advised to wait for the reasnlts of the Drug Surveillance Study of Analgia condu ted under the supervision of a c I-laborative group at Boston in the United States. While the Boston study have not pin pointed a greater absolute risk of Analgin when compared with other pain killers in terms of its alleged adverse rs-action of lowering a particular type of whits blood cells, th? Drugs Technical Advisory Board is yet to meet and rev'ew the Boston study report for giving it* considered opinion on the subject.

(c) to (e) The occurrence of ngranu-locytosis as an adver e reaction to Analgin was known right from the time the drug I was,-introduced in the market and what has been found in later years is to om-pile its i-cidence in a limited geographical population in some countries having facilities to do so. It is not that the drug was found to be specially dangerou in some countries. While some counlries hay withdrawn Analein. the drua continues to be marketed in many coun'nes. The experts consulted in India after the completion of the Boston study had considered that Analgin is a potent pain Kinerr

and when used discriminately it benefit outweighs the possible risks. However, Government, with the help of an expert committee is invest gating the rationality for continued marketing of combinations of Analgin with other drugs,

(f) It is not true that other pain killers moving in the market are totally free from side effects and every drug has its characteristic side effects.

<g) Does not arise.

**Marketing clearance for new drugs, drag combinations and vaccines**

488. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state-.

(a) whether it is a fact that both clearance for marketing of new drugs, combination drugs and vaccines as well as manufacturing permissions are granted by State drug Authorities;

(b) if so, whether it is a fact that State drugs authorities are neither having quali fied nor experienced officers to take a decision about the rationality or irrationa lity of drugs;

(C) what is the direction of the Government in regard to clearance of new drugs, combination of drugs and vaccines in the country;

(4) whether Government have proposed certain guideline in this regard; and

(e) if so, what are the details of the same?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHA-PARDE): (*a)* and (b) As per the "Guidelines on Introduction of New Drugs" combination of known drugs and vaccines would fall under the definition of "new drugs" and as such permission to market and manufacture new drugs is required to be granted by the Drugs Controller (India). However, the guidelines are not yet statutory and some States have cleared certain combinations of drugs and vaccines for marketing in consultation with their experts.

Stale Drug Control Authorities in con-sultation with experts generally license formulations.

(c) to (e) The "Guidelines on Introduction of New Drugs" gives a clear-cut definition as to what constitutes a new drug, defines the various phases of clinical trials, safety data and other pre-clin cal data that are required to be submitted for examination before clinical trials permission could be granted to an applicant. Both pre-clinical 'and clinical data that are required to be submitted for a new drug for consideration of its marketing are also given in the guidelines. It also gives the types of data that are required for consi-deration of marketing permission of various possible types of combinations.

**Linking of Sector-37, NOIDA with Kendriya Terminal by D.T.C.**

489. SHRI M. KADHARSHA; Will the Minister of SURFACE TRANSPORT be pleased to state:

(a) whether representations have been received by D.T.C. authorities recently re-garding linking of Sector-37, NOIDA with Kendriya Terminal, if so, the action taken by Government on each of such demand;

(b) whether Government propose to start some bug routes from that area for Kendriya Terminal in the near future; if so, by when; and

(c) if not, the reasons therefor?

THE MINISTER OF STATE OF THE MINISTRY OF SURFACE TRANS PORT (SHRI RAJESH PILOT): (a) to (c) Yes Sir. A trip at 0640 hrs. on Route No. 346 has been provided from Sector-37 NOIDA for Kendriya Terminal and vice-versa at 1315 hrs. There is no proposfal for further augmentation as the existing service is considered adequate.